# Application for Mammography Certification

**PLEASE PRINT OR TYPE ALL INFORMATION**

## SECTION 1—FACILITY STATUS

a. Application is for: (check one category box below and circle appropriate selection within category checked)

- ☐ Biopsy-only facility: ☐ New facility ☐ New machine ☐ Renewal
- ☐ ACR MQSA facility: ☐ New facility ☐ New machine ☐ State certificate renewal
- ☐ Change of address
- ☐ Transferring machine to different address
- ☐ Change of facility name or owner
- ☐ Changes to facility personnel: ☐ Technologists ☐ Radiologists ☐ Physicist

| b. Current FDA facility identification number | FDA certificate expiration date | c. State registration number | State certificate expiration date |
|---|---|---|---|
| | | | |

## SECTION 2—FACILITY ADDRESS INFORMATION

a. Facility name

b. D.B.A. (if applicable)

| c. Contact name | Contact title |
|---|---|
| | |

| d. Phone number | Fax number | e. Employer Identification number (Federal Tax ID number) |
|---|---|---|
| | | – |

| f. Facility location address (line 1) | g. Facility mailing address (line 1) |
|---|---|
| (address line 2) | (address line 2) |

| City | State | ZIP code | City | State | ZIP code |
|---|---|---|---|---|---|
| | | | | | |

## SECTION 3—FACILITY MAMMOGRAPHY ACCREDITATION HISTORY

a. Is this a brand new facility (have never had an FDA number)? ☐ Yes ☐ No

b. Is this facility performing only biopsy procedures, such as stereotactic, needle localizations, etc. (i.e., your facility performs no screening and/or diagnostic procedures)? ☐ Yes ☐ No

c. For this physical location address, have you previously applied for FDA MQSA certification through the American College of Radiology (ACR)? ☐ Yes ☐ No

d. Has the accreditation status of this facility ever been **denied** (including failure to pass provisional, reinstatement, or renewal periods), **revoked** or **suspended**? ☐ Yes ☐ No

- ***If yes to item d, provide a detailed written explanation and attach to this application.*** The following information must be included: (1) indicate the identity of specific machines that failed, (2) the dates of failure, (3) details of how you corrected CIR deficiencies (including any physician or technologist training and machine/processor repair) and, (4) if the machine subsequently passed CIR after corrective actions were taken.
- If the failed CIR was performed under the direction of an Accrediting Body other than the State of California (for example ACR) and occurred within the last three years, submit full copies of failure reports with this application.
- For suspensions or revocations, describe the circumstances that led to suspension or revocation.

## SECTION 4—FACILITY PROCEDURE INFORMATION

a. Do you currently accept self-referrals? ☐ Yes ☐ No

b. Number of screening procedures performed per year: _____

c. Number of diagnostic procedures performed per year: _____

d. Total number of procedures performed per year in 4b and 4c above: 0

e. Number of stereotactic procedures performed per year: _____

f. Number of needle localizations performed per year: _____

## *SECTION 5—ASSOCIATED PROGRAM INFORMATION*

a. Do you now participate or intend to participate in the Every Woman Counts Program (formerly known as BCEDP/BCCCP)? ☐ Yes ☐ No

b. Supply the nine-digit Medi-Cal number used to bill for mammographic examinations performed at this facility location address: _____

## *SECTION 6—PERSONNEL QUALIFICATIONS*

a. **Physician's qualifications** (list all physicians who interpret mammography exams for this facility):

| NAME | CALIFORNIA MEDICAL LICENSE NUMBER | SUPERVISOR/ OPERATOR CERTIFICATE NUMBER | SUPERVISOR/ OPERATOR EXPIRATION DATE | ABR, AOBR, OR RCPSC CERTIFIED IN DIAGNOSTIC RADIOLOGY? |
|---|---|---|---|---|
| 1. | | | | ☐ Yes ☐ No* |
| 2. | | | | ☐ Yes ☐ No* |
| 3. | | | | ☐ Yes ☐ No* |
| 4. | | | | ☐ Yes ☐ No* |
| 5. | | | | ☐ Yes ☐ No* |
| 6 | | | | ☐ Yes ☐ No* |
| 7. | | | | ☐ Yes ☐ No* |

*(Use additional sheets if necessary.)*

* If a physician is ***non***-ABR, -AOBR or -RCPSC certified, supply attachments documenting their qualification as an interpreting physician under Section 900.12 (a)(1) of 21 Code of Federal Regulations, Part 900. ***These must include the following initial qualifications:*** (1) attending three months full-time training in the interpretation of mammograms (provide a signed statement by the physician-preceptor who administered this training); (2) copies of certificates demonstrating 60 hours of continuing medical education in mammography (time spent in a radiology residency program will be accepted if documented in writing); and (3) documentation that they have read and interpreted 240 mammograms in the six months preceding this application.

b. **Technologist's qualifications** (list all technologists performing mammography at this facility):

| NAME (CHECK THE LEAD QA/QC TECHNOLOGIST) | STATE MAMMOGRAPHY CERTIFICATE NUMBER | CERTIFICATE EXPIRATION DATE |
|---|---|---|
| 1. ☐ | | |
| 2. ☐ | | |
| 3. ☐ | | |
| 4. ☐ | | |
| 5. ☐ | | |
| 6. ☐ | | |
| 7. ☐ | | |
| 8. ☐ | | |
| 9. ☐ | | |
| 10. ☐ | | |

*(Use additional sheets if necessary.)*

c. **Physicist's qualifications** (identify the physicist that performs required annual mammography physicist surveys):

| Mammography Medical Physicist | State Physicist registration number |
|---|---|
| | |

## SECTION 7—MAMMOGRAPHY EQUIPMENT INFORMATION

a. **Mammography Machine Listing** (Complete one line for each machine at your facility.)

| MAKE | MODEL | CONTROL SERIAL NUMBER | FACILITY ROOM NUMBER | UNIT MAP ID NUMBER ON ACR CERT INCLUDING NUMBER AFTER HYPHEN | IS THIS MACHINE MOBILE? (*see Section 7c below*) | THIS MACHINE IS USED FOR THE FOLLOWING PROCEDURES: *(Check all that apply.)* SCREENING/ DIAGNOSTIC | NEEDLE LOC | STEREO | IF STEREOTACTIC, CHECK: D = DEDICATED UNIT -OR- A = ADD-ON UNIT | MANUFACTURER AND TYPE OF FILM/SCREEN SYSTEM USED FOR THIS UNIT *AND/OR* ENTER "D" IF THIS MACHINE IS DIGITAL ONLY | *FOR OFFICE USE ONLY* XM NUMBER |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. | | | | | ☐ Yes ☐ No | ☐ | ☐ | ☐ | ☐ D ☐ A | | |
| 2. | | | | | ☐ Yes ☐ No | ☐ | ☐ | ☐ | ☐ D ☐ A | | |
| 3. | | | | | ☐ Yes ☐ No | ☐ | ☐ | ☐ | ☐ D ☐ A | | |
| 4. | | | | | ☐ Yes ☐ No | ☐ | ☐ | ☐ | ☐ D ☐ A | | |
| 5. | | | | | ☐ Yes ☐ No | ☐ | ☐ | ☐ | ☐ D ☐ A | | |

*(Use additional sheets if necessary.)*

b. **Film Processor Listing**

| MAKE | MODEL | EXTENDED PROCESSING? (Y/N) | THIS PROCESSOR IS USED FOR THE ABOVE MACHINE NUMBERS: |
|---|---|---|---|
| 1. | | ☐ Yes ☐ No | |
| 2. | | ☐ Yes ☐ No | |

*(Use additional sheets if necessary.)*

c. **Additional Requirements for *mobile* machines:**

Attach a separate sheet providing the following information. For each mobile machine, specify: (1) the address of each location where mammography will be performed; (2) the name and telephone number of the responsible person who is allowing the service to be provided at the location; (3) whether mammograms will be processed on-board or, if processed at different locations, the address of each location; (4) whether the machine is used exclusively in a mobile vehicle or, if transported to the use location and moved to the area examinations are to be performed, the designated room number within the building at each use location; and (5) a description of the quality control tests that will be performed each time the radiation machine is relocated.

## *SECTION 8—PHYSICIST REPORTS*

Attach the latest physicist report for each machine listed above. The report may not be over 12 months old. If any failures and/or recommendations are referenced in a report, attach a list of corrective actions taken to mitigate all deficiencies. Include copies of work invoices with the description of your corrective actions taken. ***Physicist's reports with deficiencies that are not accompanied by correction action reports will not be accepted.***

## *SECTION 9—ACKNOWLEDGMENT AND CERTIFICATION*

I certify to the best of my knowledge that:

a. The information contained in this application is true and correct;
b. The physicians, physicists, and technologists meet the requirements of the California Health and Safety Code, Sections 106965 through 115115. Also, those physicians, technologists, and physicists who are associated with screening/diagnostic mammography operations meet the requirements of California Code of Regulations, Title 17, Sections 30315.50, 30315.51, and 30315.52;
c. The x-ray machine(s) is/are specifically designed to perform mammography. Also, x-ray machines used for screening/diagnostic mammography comply with California Code of Regulations, Title 17, Section 30316;
d. For screening/diagnostic operations, the facility will adhere to medical records and mammography reports requirements set forth in California Code of Regulations, Title 17, Sections 30316.50, 30317.40, 30317.50, and 30319.20;
e. That, if the above-mentioned facility performs screening/diagnostic mammography, the facility has a quality assurance program that complies with California Code of Regulations, Title 17, Sections 30316.20, 30316.22, 30316.30, 30316.40, 30317.10, 30317.20, 30317.60.
f. That, if the above-mentioned facility performs interventional mammography, the facility has a quality assurance program that complies with "Rules of Good Practice for Supervision and Operation of Mammographic X-ray Equipment."
g. The Mammography Program of the Radiologic Health Branch will be notified in writing of any changes in our status to comply with California Code of Regulations, Title 17, Section 30319; and,
h. False statements or failure to report changes in our status may result in revocation of authorization to perform mammography in California as set forth in California Code of Regulations, Title 17, Section 30320.90.

| Signature of Facility Owner or Administrator | Date |
|---|---|
| | |

| Type or print name | Title |
|---|---|
| | |

***If the individual who signed above is not the Lead Interpreting Physician, the following must be completed:***

As the Lead Interpreting Physician responsible for mammography operations at this facility, I concur with all representations in this application, signed,

| Signature of Lead Interpreting Physician | Date |
|---|---|
| | |

| Type or print name | Contact phone number if different than that in Section 2d of this application |
|---|---|
| | |

**Mail completed form to:**

California Department of Health Services
Mammography Certification Program
Radiologic Health Branch, MS 7610
P.O. Box 997414
Sacramento, CA 95899-7414

For more information, go to **www.dhs.ca.gov/rhb** or phone (916) 327-5106.